

### **REMARKS**

Claim 1 has been amended to recite the purified polypeptide comprising SEQ ID NO: 1331. Claims 37 and 38 have been added. Support for the new claims may be found in the previously pending claim 1. Claims 1, 10, 26-28, 30-32, and 37-38 are pending in this application. No new subject matter has been introduced with the amendments.

Applicants thank the Examiner for the withdrawal of the rejection of claims 1, 10, 26-28 and 30-32 made in paragraph 7 of the Office Action mailed 5/20/08 under 35 U.S.C. § 112, first paragraph, in light of the amendment to claim 1.

#### **I. Objection to the specification**

The Examiner maintains the objection to the specification made in paragraph 4 of the Office Action mailed 05/20/08.

Applicants respectfully traverse the objection and its supporting remarks. When inserting subject matter that is incorporated by reference into the specification, MPEP 608.01(p) states “A statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter is also required.” The applicants have complied with this requirement. On page 4, Section I, of the Office Action response submitted October 20, 2008, the applicants stated “However, in order to facilitate prosecution of this case, applicants are filing herewith *a sequence listing which includes the same sequences as in the material incorporated by reference* appended to the end of the sequence listing.” Thus, the applicants provided a statement that the material inserted by way of the substitute sequence listing was the material previously incorporated by reference. Filed with the response was a Statement Pursuant to 37 CFR 1.821(f), which stated in the first paragraph, “The submission of the Sequence Listing *does not include new matter.*” Thus, the applicants also provided a statement that the amendment (i.e., the substitute sequence listing) does not constitute new matter. Both filings were signed by the undersigned who is a practitioner representing the applicants. Thus, applicants

respectfully assert that they have complied with the requirements of 37 CFR 1.57(g) for insertion of material incorporated-by-reference into the specification.

Applicants therefore respectfully request that the Examiner withdraw the objection.

## **II. Rejection under 35 U.S.C. 112, 1st Paragraph, written description**

Claims 1, 10, 26-28 and 30-32 are rejected under 35 U.S.C § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse the rejection and its supporting remarks. However, solely to facilitate prosecution of this case, applicants have amended claim 1 to remove the recitation “wherein said amino acid sequence of SEQ ID NO:1331 comprises at least one antigenic determinant and wherein said amino acid sequence of SEQ ID NO:1331 can detect the presence of antibodies raised against *Neisseria meningitidis* serogroup B.” Thus, applicants have rendered the rejection of claim 1 moot.

In addition, the inventors were in possession of new claims 37 and 38. Page 70 of the specification indicates that the inventors had identified 962-975 as being hydrophilic, in addition to being antigenic. Furthermore, comparison to the corresponding stretch of amino acids in an *N. meningitidis* serogroup A strain (also identified by the inventors – see, e.g., page 73) shows a high degree of conservation in the hydrophilic residues (in bold).

SEQ ID 1331 P**TQKAAELNQKSKELEQQ**

SEQ ID 1605 X**TQKXXXLNQKSKELEQQ**

Thus, the one of skill in the art would recognize that the inventors knew that the sequences were hydrophilic. Finally, all but one of the ten C-terminal amino acids is hydrophilic, so

one of skill in the art would understand that these sequences are most likely surface exposed and therefore accessible as the energetic penalty to bury these sequences within the core of orf114 would be quite high. Thus, the conservation and accessibility would lead one of skill in the art to recognize that the inventors were in possession of a polypeptide that “can detect the presence of antibodies raised against *Neisseria meningitidis* serogroup B” as claimed in dependent claim 38.

Applicants thus respectfully request withdrawal of the rejection of claims 1, 10, 26-28 and 30-32 under 35 U.S.C. § 112, first paragraph, written description as the rejection is moot.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. 223002100200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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